

Statement of New View Campaign
following the Advisory Committee meeting
on "Intrinsa" held on Dec, 2, 2004

We are extremely pleased that the FDA Reproductive Drugs Advisory Committee voted UNANIMOUSLY (17-0) to recommend AGAINST approval of "Intrinsa" at the end of their meeting in Gaithersburg, MD on December 2, 2004.

This unanimous decision accurately reflected the doubts and concerns expressed by the FDA staff and members of the Advisory Committee with regards to the drug's:

- Safety
- Effectiveness
- Marketing to untested groups of women

The FDA and the Advisory Committee raised issues of the drug's long term safety. "Intrinsa" is a testosterone patch that needs to be worn for weeks and months (and changed twice/week at an unpublished cost) before any effect is shown. It was tested against placebo for only 6 months in 1095 surgically menopausal women who were also using estrogen. This is grossly inadequate to evaluate long-term cardiovascular risk and rule out worries about breast cancer.

Promotion of "Intrinsa" to wider populations (e.g., intact menopausal women, pre-menopausal women, or women not taking estrogen) is likely, given Procter and Gamble's educational plans (shown in their continuing medical education courses and the education plan submitted to the FDA). The Advisory Committee stressed the necessity of safety in these populations as well.

The effectiveness of "Intrinsa" to improve women's sexual life was minimal, according to the FDA and the Advisory Committee. The *placebo* patch significantly elevated frequency of sexual activity and scores on questionnaires about sexual feelings, raising the interesting question of what sort of psychological encouragement and education occurred for women using the placebo patch. The testosterone patch increased scores above those of the placebo patch, but by a smaller additional increase than the increase of placebo over baseline.

This was the first drug proposed to treat women's sexual problems, and we are very pleased that the Advisory Committee chose to avoid the media circus about a so-called "Pink Viagra" and look closely at the actual scientific and medical facts. Procter and Gamble, in its rush to market, failed to prove its case, and in a hearing open to the press and the public, the limited benefits and potential dangers of the "Intrinsa" testosterone patch were clear for all to see.

The "New View" Campaign testified against "Intrinsa" on December 2. Our testimonies and the 6 factsheets we prepared are all posted on our website, <http://www.fsd-alert.org>, along with list of endorsers and contact people, a list of references and resources, and other materials.